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FDA grants Expanded Access Protocol to RLF-100 (Aviptadil) for Respiratory Failure in COVID-19: Currently in development by NeuroRx and Relief Therapeutics under Fast Track Designation

- Expanded access is available to patients who are ineligible for enrollment in the FDA clinical trial of RLF-100, including pregnant women

- RLF-100 is a patented formulation of Aviptadil (synthetic human Vasoactive Intestinal Polypeptide VIP), which inhibits pro-inflammatory cytokines and protects alveolar type 2 cells in the lungs inhibiting pro-inflammatory cytokines. Type 2 cells are essential to oxygen exchange and are preferentially targeted by the SARS-CoV-2 coronavirus

GENEVA, Switzerland and RADNOR, Pa., July 29, 2020 /PRNewswire/ -- RELIEF THERAPEUTICS Holding AG (SIX:RLF, OTC:RLFTF) "Relief" and its U.S. partner, NeuroRx, Inc. today announced that FDA has granted NeuroRx an Expanded Access Protocol for treatment of Respiratory Failure in COVID-19 with RLF-100 (aviptadil), a synthetic form of Vasoactive Intestinal Peptide. Details may be seen on www.clinicaltrials.gov NCT04453839. The protocol makes treatment available to patients who have exhausted approved therapies and are not eligible for the current phase 2/3 trial of RLF-100 because of other medical conditions and specifically makes the treatment available to pregnant women. Although the drug remains under investigation, rapid recovery from respiratory failure in COVID-19 has been seen in patients treated under FDA Emergency Use authorization.1

"By granting this Expanded Access protocol, FDA has made a potentially lifesaving drug immediately available to critically ill patients who have no other available treatment," said Dr. Jonathan C. Javitt, MD, MPH, NeuroRx's CEO. "*We thank the FDA's pulmonary division for its rapid and proactive implementation of the Coronavirus Treatment Acceleration Program and we aspire to demonstrate broad safety and efficacy for RLF-100 in our ongoing clinical trial.*"

*The SARS-CoV-2 coronavirus that causes COVID-19 attacks the body by entering the small population of Alveolar Type II cells in the lung, almost like hitting the needle in the haystack.*2 *Without Type II cells, the lung cannot transmit oxygen, which why the coronavirus causes acute respiratory failure. 50 years of scientific research demonstrates that VIP binds specifically to the Type II cell and protects that cell against cytokines (inflammatory molecules) and a wide array of toxic and infectious injuries."*3

The expanded access protocol may be viewed on www.clinicaltrials.gov NCT04453839. Physicians who wish to enroll their patients in the protocol must submit the protocol to their local investigational review board and file FDA form 1572 with NeuroRx, Inc. Further information may be obtained from expandedaccess@neurorxpharma.com.

About RELIEF THERAPEUTICS Holding AG

The Relief group of companies focus primarily on clinical-stage projects based on molecules of natural origin (peptides and proteins) with a history of clinical testing and use in human patients or a strong scientific rational. Currently, Relief is concentrating its efforts on developing new treatments for respiratory disease indications.

Relief Therapeutics holds orphan drug designations from the U.S. Food and Drug Administration and the European Union for the use of VIP to treat ARDS, pulmonary hypertension, and sarcoidosis. Relief Therapeutics

also holds a U.S. patent4 for RLF-100 and proprietary manufacturing processes for its synthesis.

RELIEF THERAPEUTICS Holding AG is listed on the SIX Swiss Exchange under the symbol RLF.

About NeuroRx, Inc.

NeuroRx draws upon more than 100 years of collective drug development experience and is led by former senior executives of Johnson & Johnson, Eli Lilly, Pfizer, and AstraZeneca, PPD. In addition to its work on RLF-100, NeuroRx has been awarded Breakthrough Therapy Designation and a Special Protocol Agreement to develop NRX-101 for the treatment of suicidal bipolar depression and is currently in Phase 3 trials. Its Board of Directors and Advisors includes Hon. Sherry Glied, former Assistant Secretary, U.S. Dept. of Health and Human Services; Mr. Chaim Hurvitz, former President of the Teva International Group, Lt. General HR McMaster, the 23rd National Security Advisor, Wayne Pines, former Associate Commissioner of the U.S. Food and Drug Administration, Judge Abraham Sofaer, and Daniel Troy, former Chief Counsel, U.S. Food and Drug Administration.

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4US 8,178,489 Formulation for Aviptadil

View original content:http://www.prnewswire.com/news-releases/fda-grants-expanded-access-protocol-to-rlf-100-aviptadil-for-respiratory-failure-in-covid-19-currently-in-development-by-neurorx-and-relief-therapeutics-under-fast-track-designation-301101816.html

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